October 3, 2017

Veru Inc. Announces Agreement with Timm Medical Technologies, LLC to Distribute and to Promote PREBOOST

MIAMI, Oct. 03, 2017 (GLOBE NEWSWIRE) -- Veru Inc. (Nasdaq:VERU), a biopharmaceutical company focused on urology and oncology, today announced it has signed a United States distribution and co-promotion agreement with Timm Medical Technologies for PREBOOST® (4% benzocaine wipes) for the prevention of premature ejaculation. Veru grants Timm Medical Technologies distribution and promotion rights of PREBOOST® in the United States and its territories, and Veru retains rights to also distribute and promote PREBOOST® sales in the US.

Timm Medical Technologies is a medical device and pharmaceutical company specializing in marketing and sales of men's health products including STENDRA® (avanafil tablets) and ERECAID® to over 3,000 urology practices in US. Timm Medical Technologies has approximately 32 sales representatives that will promote PREBOOST® to urologists.

As reported in May 2017, Veru reported positive results from a Phase 4 clinical study of PREBOOST®. The Phase 4 double-blind, randomized, placebo-controlled clinical study met its primary endpoint of change in average Intravaginal Ejaculatory Latency Time (IELT) of 5.5 minutes at two months ($p<0.001$), as well as secondary outcomes of change in questionnaire assessments including global rating of distress, medication assessment and Index of Premature Ejaculation (IPE). After treatment with PREBOOST®, 82 percent of men were no longer considered to have premature ejaculation.

Timm will target urology practices as well as over the counter (OTC) websites such as www.PREBOOST.com to develop product awareness and to set up distribution of PREBOOST® directly to patients from physicians' offices.

"Timm Medical is a well-known specialty pharmaceutical company with an impressive marketing and sales record focusing on erectile dysfunction and men's health. They also have an extensive database of urology medical practitioners and independent distributors who will increase awareness of and patient access to PREBOOST®," said Mitchell Steiner, MD, President and CEO of Veru, Inc. "Both organizations target urological markets. We are pleased to be working with Timm Medical Technologies to significantly expand the scope of marketing and sales activities and patient access to PREBOOST®."

"We are excited to partner with Veru on the sale of PREBOOST® and further our mission of

providing urologists with solutions for their patients," said Andy Gesek, President of Timm Medical Technologies, Inc. "Urologists will now have the option to offer a viable treatment to their patients who suffer from premature ejaculation."

About Premature Ejaculation

According to the International Society for Sexual Medicine (ISSM), premature ejaculation (PE) is the most common sexual dysfunction in men, even more common than erectile dysfunction. The ISSM defines PE as persistent or recurrent ejaculation with minimal sexual stimulation before, on, or shortly after penetration and before the person wishes it to happen. Estimates of prevalence range significantly; however, most experts estimate the prevalence rate at 20-30 percent of men, as it can affect men of all ages and it is the most commonly observed sexual disorder in men below 40 years of age. The condition is especially debilitating because many men who suffer from PE also report a significant impact on partners and relationships.

About PREBOOST® (4% benzocaine wipes)

PREBOOST® is a proprietary OTC male genital desensitizer used for the treatment of PE. There are no prescription products for PE approved by the United States FDA. Off-label use of antidepressants and PDE-5 inhibitors have been used with limited success because of inconsistent efficacy and unacceptable side effects. Psychological counseling and behavioral therapy are also used with mixed results. Of the consumer health products, the topical anesthetics are administered as sprays and gels. The drawbacks of these approaches include inconsistent dosing leading to too much anesthetic and transference of the anesthetics to the partner. PREBOOST® is compliant with the FDA monograph and is approved in the United States. PREBOOST® is the only individually packaged medicated wipe that contains a desensitizing agent (benzocaine 4.0%). The advantages are: 1) Convenient individually wrapped wipes so it is easier to carry and to be discreet, 2) The correct dose is delivered each time 3) The medicine is applied topically and dries quickly which prevents the potential for transference to partner, and 4) Benzocaine at 4.0% temporarily desensitizes, but does not completely numb the penis.

The PREBOOST® Clinical Study enrolled 26 men aged 18 years or older in a heterosexual, monogamous relationship, with PE, defined as reported poor control over ejaculation, personal distress related to ejaculation and average IELT of two minutes or less on stopwatch measurement. Subjects were randomized 2:1 to treatment with benzocaine wipes or placebo wipes, with men in the placebo group crossed over to the treatment group one month after randomization. The primary outcome measure for the study was change in IELT at two months, with secondary outcomes including change in questionnaire assessments of global rating of distress, medication assessment and IPE. Data showed that patients treated with benzocaine 4% wipes demonstrated a statistically significant improvement in IELT after the first month of treatment (2.75 minutes), with greater improvement after the second month (5.5 minutes), compared to placebo (1.8 minutes). Men in the treatment group also reported greater improvement in distress relating to intercourse, control of ejaculation and satisfaction with sexual intercourse over the study period. After treatment with PREBOOST®, 82 percent of men were no longer considered to have premature ejaculation. Results showed that treatment was well tolerated. PREBOOST® is available for sale in the U.S. at www.PREBOOST.com.

About Veru Inc.
Veru Inc. (Veru) is a biopharmaceutical company focused on urology and oncology. Veru utilizes FDA's 505(b)(2) regulatory approval pathway to develop and commercialize drug candidates. FDA's 505(b)(2) regulatory approval pathway is designed to allow for potentially expedited regulatory approval based on a previously established safety and efficacy profile of the product. Veru is developing products under the 505(b)(1) pathway as well, which is the traditional new drug application (NDA) pathway. The company is currently developing drug product candidates for benign prostatic hyperplasia (BPH or enlarged prostate), hot flashes associated with prostate cancer hormone treatment, male infertility and novel oral chemotherapy (alpha & beta tubulin inhibitor) for a variety of malignancies, including metastatic prostate, breast and ovarian cancers. In addition, the company markets and sells the FC2 Female Condom® (now available by prescription in the US including through the virtual doctor smartphone app "HeyDoctor" at www.fc2.us.com) and PREBOOST® medicated individual wipe, which is a male genital desensitizing drug product for the prevention of premature ejaculation.

The company's division, The Female Health Company, is focused on the global public health sector FC2 business. This division markets the company's Female Condom (FC2) to entities, including ministries of health, government health agencies, U.N. agencies, nonprofit organizations and commercial partners, that work to support and improve the lives, health and well-being of women around the world.

More information about Veru and its products can be found atwww.veruhealthcare.com, www.PREBOOST.com and www.fc2.us.com. For corporate and investor-related information about the Company, please visit https://veruhealthcare.com/investors.

About Timm Medical Technologies, Inc.
Timm Medical Technologies, Inc. (Timm) is a privately held Medical Device and Pharmaceuticals company headquartered in Fort Washington, PA. Timm's mission is focused on providing a variety of men's sexual health treatment options to Urologists and ultimately their patients. More information about Timm and its products can be found at www.TimmMedical.com.

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:
The statements in this release that are not historical fact are "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. Any forward-looking statements in this release are based upon the Company's current plans and strategies, and reflect the Company's current assessment of the risks and uncertainties related to its business, and are made as of the date of this release. The Company assumes no obligation to update any forward-looking statements contained in this release as a result of new information or future events, developments or circumstances. Such forward-looking statements are inherently subject to known and unknown risks and uncertainties. The Company's actual results and future developments could differ materially from the results or developments expressed in, or implied by, these forward-looking statements. Factors that may cause actual results to differ materially from those contemplated by such forward-looking statements include, but are not limited to, the following: product demand and market acceptance; competition in the Company's markets and the risk of new competitors and new competitive product introductions; risks relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations;

risks related to the development of the Company's product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market; many of the Company's products are at an early stage of development and the Company may fail to successfully commercialize such products; risks related to intellectual property, including licensing risks; government contracting risks, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts, process errors, politics or other pressures, and the risk that government tenders and contracts may be subject to cancellation, delay or restructuring; a governmental tender award indicates acceptance of the bidder's price rather than an order or guarantee of the purchase of any minimum number of units, and as a result government ministries or other public sector customers may order and purchase fewer units than the full maximum tender amount; the Company's reliance on its international partners in the consumer sector and on the level of spending on the female condom by country governments, global donors and other public health organizations in the global public sector; the economic and business environment and the impact of government pressures; risks involved in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers; the Company's production capacity, efficiency and supply constraints; risks related to the costs and other effects of litigation; the Company's ability to identify, successfully negotiate and complete suitable acquisitions or other strategic initiatives; the Company's ability to successfully integrate acquired businesses, technologies or products; and other risks detailed in the Company's press releases, shareholder communications and Securities and Exchange Commission filings, including the Company's Form 10-K for the year ended September 30, 2016. These documents are available on the "SEC Filings" section of our website at www.veruhealthcare.com/investors.

Contact:
Kevin Gilbert
Veru Inc.
786-322-2213
KGilbert@veruhealthcare.com

Matt Beck
The Trout Group LLC
646-378-2933
MBeck@troutgroup.com

Source: Veru Inc.